

**Evaluation of Success in Neuraxial Block Placement between using Palpation of Landmark versus
Pocket-Size Handheld Ultrasound (U/S) Method**

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Research Protocol:

Title: Evaluation of Success in Neuraxial Block Placement between using Palpation of Landmark versus Pocket-Size Handheld Ultrasound (U/S) Method.

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Introduction:

Administration of (neuraxial blocks) spinal and epidural blocks is commonly achieved by first palpating the landmarks for midline with spinous process and iliac crest for L3-4-5 intervertebral spaces. With an epidural block, a loss of resistance in a pressurized syringe is used to incrementally advance the epidural needle until identification of epidural space with loss of resistance in the pressurized syringe. With a spinal block, the spinal needle is advanced incrementally until a noted “feel” of dural puncture together with return of spinal fluid via the spinal needle. The palpation technique and somewhat “blind” technique to identify the spinal and epidural spaces become more difficult and less reliable particularly with the increasing prevalence of the morbid and super-morbid obese patients. Ultrasound devices have become common and successful with non-neuraxial blocks and venous accesses, both involving mostly non-bony, soft tissues. Application of conventional ultrasound for neuraxial blocks has been limited by its bulkiness, limited imaging for bony structures and lack of automated artificial intelligent algorithm for pattern recognition. Recent technological advancement has addressed the aforementioned limitations. Rivanna Accuro is one such device that has gained FDA approval and may have helped in addressing some of these issues. It is a handheld (pocket size) U/S device with real time pattern recognition for bony structures such as the spine while providing 3-D overlay for recognition of the midline spinous process and epidural spaces and distance. We hypothesize that the Rivanna Accuro or similar U/S device would reduce time to success of identifying epidural and/or intrathecal spaces as compared to conventional palpation method. Thus, we are performing a pilot study for this.

Method:

After written informed consent, 120 evaluable subjects (60 parturients requesting neuraxial labor analgesia, 60 patients undergoing neuraxial anesthesia for cesarean delivery) will be enrolled. Inclusion criteria including BMI >30. Exclusion criteria include absolute contraindications for neuraxial block or allergy to gel used for ultrasound devices. The subjects will be randomized into one of two groups: group P (Palpation) and group R (Rivanna Accuro U/S). When the subject is ready for neuraxial procedure, the location for the epidural or spinal needle insertion will be identified by both palpation using conventional landmarks (spinous process and iliac crest), and with Rivanna Accuro U/S device. In

addition, the automated measurement of depth to epidural space and spinous process will be recorded. The distance between the needle insertion site found with either method will be recorded (both vertical and horizontal distance difference). Those in group P, the neuraxial block will be performed as in the usual method using the needle insertion site identified with palpation. For subjects in group R, the needle insertion site will be the site identified by the Rivanna Accuro U/S device. After placement of neuraxial labor analgesia or spinal anesthesia, the usual standard dose of medication will be administered as in usual manner for patients regardless in this study or not. The primary outcome measure is the time it takes to successfully identify the epidural space (defined by loss of resistance) and spinal fluid flow with spinal needle. Secondary outcome measures include number of needle pass to success, number of first attempt success, and deviation of final needle insertion site from initial site, depth to successful epidural space and intrathecal space.

Risk:

The usual risk of neuraxial analgesia and anesthesia would have been the same as if the subject has not participated in this study and would have been explained to the subject by the anesthesia provider before consenting and enrolling in this study. There is no foreseeable additional risk with enrolling in this study other than it may take 1-5 minutes time to define the initial proposed needle insertion site with both palpation and U/S method.

Confidentiality and Privacy

Subjects will be assigned a sequential number as they are consented in order to de-identify the medical and demographic information that will be retrieved about their labor analgesia.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data. There is a Data Safety Monitoring committee consisting of an on-site Obstetric Anesthesiologist, a Gynecologist, and an Anesthesiologist. A summary of the research will be reported to the DSMC on a bi-annual basis, or as needed, if in-between.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

Statistics

This is a pilot study, the primary outcome will be time to success of neuraxial block placement. The time to successful placement of the epidural/CSE block in the laboring population is defined as the time of initial insertion of the epidural needle to the time of the identified epidural space confirmed by the loss of resistance and later functional block and analgesia. The time to successful placement of a spinal block

for the cesarean delivery subjects is defined as the time of initial insertion of the spinal needle to the time of identified intrathecal space confirmed by clear cerebral spinal fluid return via the spinal needle.

We estimate a 20% reduction in time of block placement and estimate a sample size of 30 per group would be needed to detect the difference with power of 0.8 and alpha of 0.05. Two groups of 30 subjects each will be enrolled from laboring patients requesting neuraxial labor analgesia; and two groups of 30 subjects each will be enrolled for cesarean delivery patients requiring neuraxial anesthesia.